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| Application Number | 10/628,734 |
| Filing Date | 07/28/2003 |
| First Named Inventor | James E. Hagstrom, et al. |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 13.3.6 |

Total Number of Pages in This Submission **161****ENCLOSURES (check all that apply)**

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Remarks

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| Firm or Individual name | Mirus Corporation |
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| Date | 08/02/2004 |

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: **James E. Hagstrom,**)
Jon A. Wolff, Sean D. Monahan,)
David B. Rozema, Vladimir G. Budker)
Paul M. Slattum, David L. Lewis)

Serial No.: **10/628,734**)

Filed: **07/28/2003**)

Group Art Unit:)

For: **Intravascular Delivery of Non-Viral Nucleic Acid**

INFORMATIONAL STATEMENT

Commissioner of Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449.

United States Patents

| <u>patent no.</u> | <u>inventor</u> | <u>issue date</u> |
|-------------------|--------------------|-------------------|
| 5,698,531 | Nabel et al. | 12/6/97 |
| 5,521,291 | Curiel, David T | 05/28/96 |
| 5,580,859 | Felgner, Philip L. | 12/03/96 |
| 5,583,020 | Sullivan, Sean | 12/1/96 |
| 5,922,687 | Mann, Micheal | 07/13/99 |

International Patents

| <u>patent no.</u> | <u>inventor</u> | <u>issue date</u> |
|-------------------|-----------------|-------------------|
| PCT/US98/27072 | | 07/01/99 |

References Cited

- Acsadi, G., Jiao, S., Jani, A., Duke, D., Williams, P., Chong, W., Wolff, J.A. Direct gene transfer and expression into rat heart in vivo. *The New Biologist* 3(1), 71-81, 1991.
- Barron, LG. Et al., "Cationic Lipids Are Essential For Gene Delivery Mediated By Intravenous Administration of Lipoplexes." *Gene Therapy* 1999/6; pp.1179-1183.
- Bohm, W. Et al., "Routes of Plasmid DNA Vaccination That Prime Murine Humoral and Cellular Immune Responses." *Vaccine* 1998; Vol. 16, No. 9/10; pp. 949-954.
- Budker, V. Et al., "Naked DNA Delivered Intraportally Expresses Efficiently in Hepatocytes." *Gene Therapy* 1996; 3; pp. 593-598.
- Budker, V. Et al., "The Efficient Expression of Intravascularly Delivered DNA in Rat Muscle." *Gene Therapy* 1998;5; pp. 272-276.
- Chapman G et al. "Gene transfer into coronary arteries of intact animals with a percutaneous balloon catheter," *Circ. Res*; 1992 Vol. 71 pp. 27-33
- Coll, Jean-Luc. Et al., "In Vivo Delivery to Tumors of DNA Complexed With Linear Polyethylenimine." *Human Gene Therapy* July 1, 1999; 10; pp. 1659-1666.
- Goula, D. Et al., "Polyethylenimine-Based Intravenous Delivery of Transgenes to Mouse Lung." *Gene Therapy* 1998/5; pp.1291-1295.
- Greelish JP et al. "Stable restoration of the sarcoglycan complex in dystrophic muscle perfused with histamine and a recombinant adeno-associated viral vector." *Nature*; 1999 Vol. 5 no. 4 pp. 439-443
- Kawabata, K. Et al., "The Fate of Plasmid DNA After Intravenous Injection in Mice: Involvement of Scavenger Receptors in Its Hepatic Uptake." *Pharmaceutical Research* 1995; Vol. 12, No. 6; pp. 825-830.
- Liu F et al. "Hydrodynamics-based transfection in animals by systemic administration of plasmid DNA," *Gene Ther*; 1999 Vol. 6 pp. 1258-1266
- Liu, Yong Et al., "Cationic Liposome-Mediated Intravenous Gene Delivery." *The Journal of Biological Chemistry* October 20, 1995; Vol. 270, No. 42; pp. 24864-24870.
- McLean, John W. Et al., "Organ-Specific Endothelial Cell Uptake of Cationic Liposome-DNA Complexes in Mice." *The American Physiological Society* 1997; pp. H387-H404.
- Milas M et al. "Isolated limb perfusion in the sarcoma-bearing rat: a novel preclinical gene delivery system," *Clin Cancer Res*; 1997 Vol. 3 no. 12 Pt. 1, pp. 2197-203
- Song, YK. Et al., "Enhanced Gene Expression in Mouse Lung by Prolonging the Retention Time of Intravenously Injected Plasmid DNA." *Gene Therapy* 1998; 5; pp. 1531-1537.
- Soriano P et al. "Targeted and nontargeted liposomes for in vivo transfer to rat liver cells of a plasmid containing the preproinsulin I gene," *PNAS*; 1983 Vol. 80 pp. 7128-7131
- Trubetskoy VS, Slattum PM, Hagstrom JE, Wolff JA, Budker VG. Quantitative assessment of DNA condensation. *Anal Biochem.* 1999; 267: 309-313.

Von Der Leyen, Heiko, E., Et al., "A Pressure-Mediated Nonviral Method For Efficient Arterial Gene and Oligonucleotide Transfer." Human Gene Therapy; September 20, 1999; vol. 10; pp. 2355-2364.

Zhang, Guofeng Et al., "Expression of Naked Plasmid DNA Injected Into the Afferent and Efferent Vessels of Rodent and Dog Livers." Human Gene Therapy October 10, 1997; 8; pp. 1763-1772.

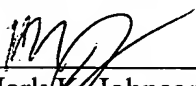
Zhang G et al. "High Levels of Foreign Gene Expression in Hepatocytes after Tail Vein Injections of Naked Plasmid DNA," Human Gene Therapy; 1999 Vol. 10 pp. 1735-1737

Zhang et al. "Efficient expression of naked dna delivered intraarterially to limb muscles of nonhuman primates," Human Gene Therapy 2001 Vol. 12 no. 4 pp. 427-438

Zhu, Ning Et al., "Systemic Gene Expression After Intravenous DNA Delivery Into Adult Mice." Science July 9, 1993; Vol. 261; pp. 209-211.

Applicant respectfully requests that these publications be expressly considered during the prosecution of this application and made of record herein and appear among the 'References Cited' on any patent to issue herefrom.

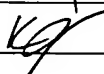
Respectfully submitted,

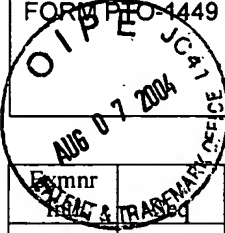


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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT FORM PTO-4449  | Attorney Docket No.: Mirus.013.03.6 | Serial No.: 10/628,734 |
| | Applicant: James E. Hagstrom, Jon A. Wolff, Sean D. Monahan, David B. Rozema, Vladimir G. Budker, Paul M. Slatum, David L. Lewis | Group: |
| | | Examiner: Joseph Weitach |

U.S. PATENT DOCUMENTS

| Patent Number | Issue Date | Patentee | Class | Sub Class | Filing Date |
|---------------|------------|--------------------|-------|-----------|-------------|
| 5,698,531 | 12/6/97 | Nabel et al. | 514 | 44 | 01/23/ 1995 |
| 5,521,291 | 05/28/96 | Curiel, David T | 530 | 391.7 | 12/15/1993 |
| 5,580,859 | 12/03/96 | Felgner, Philip L. | 514 | 44 | 03/18/1994 |
| 5,583,020 | 12/1/96 | Sullivan, Sean | 435 | 458 | 11/19/1993 |
| 5,922,687 | 07/13/99 | Mann, Micheal J. | 514 | 44 | 11/17/1996 |

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

| Document Number | Publication Date | Country or Patent Office | Class | Sub Class | Transl. yes no |
|-----------------|------------------|--------------------------|-------|-----------|-------------------|
| PCT/US98/27072 | 07/01/99 | United States | A01N | 43/04 | |

OTHER DOCUMENTS (Including Author, Title, Date Pertinent Pages, etc.)

| | |
|--|---|
| | Acsadi, G., Jiao, S., Jani, A., Duke, D., Williams, P., Chong, W., Wolff, J.A. Direct gene transfer and expression into rat heart in vivo. <i>The New Biologist</i> 3(1), 71-81, 1991. |
| | Barron, LG. Et al., "Cationic Lipids Are Essential For Gene Delivery Mediated By Intravenous Administration of Lipoplexes." <i>Gene Therapy</i> 1999/6; pp.1179-1183. |
| | Bohm, W. Et al., "Routes of Plasmid DNA Vaccination That Prime Murine Humoral and Cellular Immune Responses." <i>Vaccine</i> 1998; Vol. 16, No. 9/10; pp. 949-954. |
| | Budker, V. Et al., "Naked DNA Delivered Intraportally Expresses Efficiently in Hepatocytes." <i>Gene Therapy</i> 1996; 3; pp. 593-598. |
| | Budker, V. Et al., "The Efficient Expression of Intravascularly Delivered DNA in Rat Muscle." <i>Gene Therapy</i> 1998;5; pp. 272-276. |
| | Chapman G et al. "Gene transfer into coronary arteries of intact animals with a percutaneous balloon catheter," <i>Circ. Res</i> ; 1992 Vol. 71 pp. 27-33 |
| | Coll, Jean-Luc. Et al., " <i>In Vivo</i> Delivery to Tumors of DNA Complexed With Linear Polyethylenimine." <i>Human Gene Therapy</i> July 1, 1999; 10; pp. 1659-1666. |
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| | Liu F et al. "Hydrodynamics-based transfection in animals by systemic administration of plasmid DNA," <i>Gene Ther</i> ; 1999 Vol. 6 pp. 1258-1266 |
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| | McLean, John W. Et al., "Organ-Specific Endothelial Cell Uptake of Cationic Liposome-DNA Complexes in Mice." <i>The American Physiological Society</i> 1997; pp. H387-H404. |
| | Milas M et al. "Isolated limb perfusion in the sarcoma-bearing rat: a novel preclinical gene delivery system," <i>Clin Cancer Res</i> ; 1997 Vol. 3 no. 12 Pt. 1, pp. 2197-203 |
| | Song, YK. Et al., "Enhanced Gene Expression in Mouse Lung by Prolonging the Retention Time of Intravenously Injected Plasmid DNA." <i>Gene Therapy</i> 1998; 5; pp. 1531-1537. |
| | Soriano P et al. "Targeted and nontargeted liposomes for in vivo transfer to rat liver cells of a plasmid containing the preproinsulin I gene," <i>PNAS</i> ; 1983 Vol. 80 pp. 7128-7131 |

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| | | Trubetskoy VS, Slatum PM, Hagstrom JE, Wolff JA, Budker VG. Quantitative assessment of DNA condensation. Anal Biochem. 1999; 267: 309-313. |
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| | | Zhang, Guofeng Et al., "Expression of Naked Plasmid DNA Injected Into the Afferent and Efferent Vessels of Rodent and Dog Livers." Human Gene Therapy October 10, 1997; 8; pp. 1763-1772. |
| | | Zhang G et al. "High Levels of Foreign Gene Expression in Hepatocytes after Tail Vein Injections of Naked Plasmid DNA," Human Gene Therapy; 1999 Vol. 10 pp. 1735-1737 |
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| | | Zhu, Ning Et al., "Systemic Gene Expression After Intravenous DNA Delivery Into Adult Mice." Science July 9, 1993; Vol. 261; pp. 209-211. |

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| Examiner: | Date Considered: |
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